GE Medical Systems, LLC
% Mr. Brian R. Zielski
Regulatory Affairs Leader
3200 N. Grandview Blvd
WAUKESHA WI 53188

January 18, 2019

Re: K183231
Trade/Device Name: SIGNA Premier
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI and MOS
Dated: November 19, 2018
Received: November 20, 2018

Dear Mr. Zielski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183231

Device Name
SIGNA Premier

Indications for Use *(Describe)*

The SIGNA Premier system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the SIGNA Premier system reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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GE Healthcare
510(k) Premarket Notification Submission
K183231

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 19, 2018
Submitter:	GE Medical Systems, LLC (GE Healthcare) 3200 N. Grandview Blvd., Waukesha, WI 53188 USA
Primary Contact Person:	Brian R. Zielski Regulatory Affairs Leader GE Healthcare Phone: 262-521-6609
Secondary Contact Person:	James McMahon Senior Director, Regulatory Affairs GE Healthcare Phone: 508-382-2858
Device Trade Name:	SIGNA Premier
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code:	LNH, LNI, MOS
Predicate Device(s):	SIGNA Premier (K171128)
Device Description:	SIGNA Premier is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times, and is designed for improved patient comfort and workflow. The system features a 3.0T superconducting magnet with a 70cm bore size and can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences, imaging techniques and reconstruction algorithms. The system is designed to conform to NEMA DICOM

	standards (Digital Imaging and Communications in Medicine). The modifications to this system include the **AI**Rx software features, which allows users the flexibility to automate and standardize a number of connected steps required for an MRI examination of the brain.
Indications for Use	The SIGNA Premier system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the SIGNA Premier system reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.
Comparison of Indications for Use	The indications for use statement and intended use are identical to the predicate device, in accordance with the FDA's guidance document "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*", dated 28 July 2014.
Technology:	The SIGNA Premier with the proposed software feature employ the same fundamental technology as the predicate device. The SIGNA Premier has been modified to include the **AI**Rx feature, which automates and standardizes a number of connected steps required for an MRI examination of the brain. **AI**Rx was developed using deep learning algorithms.

	These technological differences do not raise any different questions regarding safety and effectiveness. Both devices must allow for an effective method to setup an appropriate scan prescription. The performance data described in this submission include results of both bench testing and clinical testing that show the performance of the SIGNA Premier compared to the predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The modifications to SIGNA Premier include the **AI**Rx software only feature and complies with the following voluntary standards: • IEC 62304 • ANSI/AAMI 60601-1 • IEC 60601-2-33 The following quality assurance measures were applied to the development of the subject device, as they were for the predicate device: • Risk Analysis • Requirements Reviews • Design Reviews • Integration testing (System verification) • Performance testing (Verification) • Simulated use testing (Validation) The non-clinical tests have been summarized in the verification and validation testing for **AI**Rx. The testing was completed with passing results per pass/fail criteria defined in the test cases. This supports substantial equivalence to its predicate because it was also developed under quality assurance Design Controls. In addition, the software complies with the same applicable Standards. Summary of Clinical Tests: Internal scans were conducted as part of validation for **AI**Rx workflow to confirm the productivity and consistency benefits of the proposed feature. The **AI**Rx feature is a pre-scan algorithm, and the MR System

	maintains the same imaging performance results as its predicate device (K171128).
Conclusion:	The SIGNA Premier with the modified software feature has the same intended use as the predicate. This 510(k) submission includes information on the technological characteristics of the proposed software feature, as well as performance data demonstrating that the feature is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness. In conclusion, GE Healthcare considers the SIGNA Premier to be as safe, as effective, and performance is substantially equivalent to the predicate devices.